

Milan, January 17, 2024

RE: EudraCT 2021-000-382-32**A multicentre, randomized, double-blind, placebo-controlled phase 2 study to assess the efficacy and safety of oral reparixin in cancer-related fatigue in patients with locally advanced or metastatic breast cancer undergoing taxane-based chemotherapy****Dear Sir or Madam,**

This letter is to confirm that the clinical trial REP0121 with EudraCT number 2021-000382-32 on the treatment of cancer-related fatigue was closed. Dompé farmaceutici s.p.a. (the Sponsor) ended the trial early due to encountering difficulties in enrolment due continuous and rapid oncology drug evolution, and feasibility of target patient population.

No patients were enrolled on REP0121.

The Sponsor already notified the closure of the study to the concerned Ethics Committee on 20 September 2022 and the Competent Authority on 23 September 2022.

The Sponsor performed a diligent review of the study status to decide on the future of the study, and ultimately deciding to end it.

If you have any questions or require additional information, please contact Sarah Fenlon at the following email: sarahjane.fenlon@dompe.com.

We ask that this letter is filed with the study record.

Kind regards,

DocuSigned by:

Sarah Jane Fenlon

Signer Name: Sarah Jane Fenlon
Signing Reason: I am the author of this document
Signing Time: 17-Jan-2024 | 2:09:41 PM CET

Sarah Jane Fenlon CEF2E7E5DED1445BABC17B6CABA12299

Global Regulatory affairs Director - NETosis

Dompé farmaceutici s.p.a.

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